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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	:	Confirmation No.: 3480
Harry R. Davis et al.	:	Examiner: Shengjun Wang
	:	
Application No.: 10/057,646	:	Group Art Unit: 1617
	:	
Filed: January 25, 2002	:	Atty. Docket No.: CV01379K US
	:	(4686-045566)
	:	
For: Combinations of Nicotinic Acid	:	Date: August 4, 2006
And Derivatives Thereof And	:	
Sterol Absorption Inhibitor(s)	:	
And Treatments For Vascular	:	
Indications	:	

**VIA FACSIMILE: 571-273-8300**

Mail Stop Amendment

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**DECLARATION OF MARGARET VAN HECK, PH.D.**

I, Margaret van Heck, declare and state that:

1. I obtained a Bachelor of Science in Nutritional Sciences degree from the University of Delaware in 1985.

2. I obtained a Doctorate Degree in Nutritional Biochemistry from Cornell University in 1990.

3. I am employed by Schering-Plough Research Institute ("Schering") as an Associate Director in the field of Cardiovascular and Metabolic Disease and have been previously employed by Schering since 1992.

(W0269303.1)

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4. My duties at Schering have included cardiovascular drug discovery and basic research in lipid absorption and metabolic disease.

5. A study was conducted under my supervision to determine the effect on serum triglycerides of the combination of ezetimibe with niacin in diet-induced obese mice. Male C57BL/6 mice were fed a high fat diet (45% kcal fat) for 12 months and were given a single oral dose of the compounds specified in Table 1 below. Serum triglyceride levels were evaluated one hour post-dose. Ezetimibe alone did not significantly reduce triglyceride levels, niacin alone reduced levels 23.7% and the combination of ezetimibe and niacin reduced serum triglycerides by 31.6%.

**TABLE 1**

Group	Serum Triglyceride Levels (mg/dl)
Control	54.52 $\pm$ 3.23
Ezetimibe (10 mg/kg)	49.74 $\pm$ 2.22
Niacin (100 mg/kg)	41.59 $\pm$ 3.44 * (-23.7%)
Ezetimibe + Niacin	37.29 $\pm$ 3.21 * (-31.6%)

\* p<0.05

In my opinion, these results indicate that the combination of ezetimibe with niacin (or other nicotinic acid receptor agonists) enhances the ability of niacin to reduce serum triglyceride levels, and combination of ezetimibe and niacin will prevent vascular complications greater than either agent alone.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

August 1, 2006

Margaret van Heck  
Margaret van Heck, Ph.D.